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510K SUMMARY

10-SEP-2002

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	<b>SPECIAL 510(k) SLEEP SYSTEM</b>
<b>SPECIAL 510(k) DEVICE MODIFICATION</b>	<b>JUNE 17, 2002</b> PAGE 49 of 53

## Section F – 510(k) SUMMARY

SEP 10 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR § 807.92.

**Name:** Cameron Mahon  
Vice President, Customer Satisfaction

**Address:** **XLTEK**  
2568 Bristol Circle  
Oakville, Ontario  
Canada, L6H 5S1

**Telephone:** (905) 829-5300

**Fax:** (905) 829-5304

**E-mail:** research@xltek.com

**Common Names:** Sleep Headbox

**Classification Name:** Electroencephalograph

**Predicate Devices:** XLTEK PSG-40 Polysomnography Headbox  
K9991900  
  
Masimo Radical Pulse Oximeter  
K992340/K000126  
  
XLTEK Ambulatory EEG  
K982479

**Description:** The SLEEP Headbox is a digital polysomnograph headbox used in conjunction with XLTEK SLEEP Software to acquire and review sleep recordings (polysomnography).

 	<b>SPECIAL 510(K)</b> <b>SLEEP SYSTEM</b>
<b>SPECIAL 510(K) DEVICE MODIFICATION</b>	<b>JUNE 17, 2002</b> <b>PAGE 50 of 53</b>

**Substantial Equivalence:** The SLEEP Headbox is substantially equivalent to the XLTEK PSG-40 (K991900) incorporating Masimo pulse oximetry technology (K992340/K0000126). It comprises circuitry that is substantially equivalent to the XLTEK Ambulatory EEG (K982479). These modifications do not affect the predicate device's intended use, safety, or fundamental scientific technology.

#### **Indications for Use:**

The Sleep Headbox works in conjunction with Excel Tech Sleep software. This Sleep System is used to acquire and review sleep recordings (polysomnography) in research or clinical environments for:

- Digital recording of high-level output signals (such as EEG, respiratory and oximetry signals) from conventional polygraphic recorders, signal transducers or amplifiers.
- Selection of recorded signal sections for on-screen review, annotation and marking of sleep stages.
- Computer-assisted event marking and quantitative analysis of EEG, respiratory and oximetry signals.
- Computer-assisted reporting of simple measures obtained from the recorded signals (such as magnitude, time and frequency and simple statistical measures of marked events)

The SLEEP System is not intended to replace conventional devices or methods used for sleep monitoring in critical care or intraoperative settings.

The SLEEP System requires competent user input, and its output must be reviewed and interpreted by trained polysomnographers or trained medical professionals who will exercise professional judgment in using this information.

The SLEEP System does not make any judgment of normality or abnormality of the displayed signals or the result of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 10 2002

Excel Tech, LTD.  
Sonja Markez  
Regulatory Affairs  
2568 Bristol Circle  
Oakville, Ontario  
Canada L6H 5S1

Re: K022037

Trade/Device Name: XLTEK Sleep System  
Regulation Number: 882.1400; 870.2700  
Regulation Name: Electroencephalograph; oximeter  
Regulatory Class: Class II  
Product Code: GWQ; DQA  
Dated: August 9, 2002  
Received: August 12, 2002

Dear Ms. Markez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

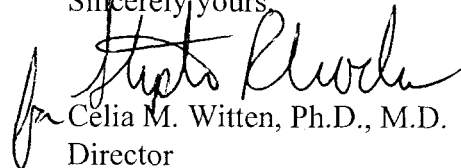
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Sonja Marquez

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

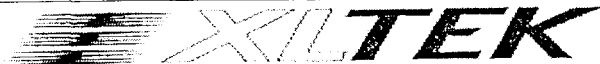
Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

	<b>SPECIAL 510(k)</b> <b>SLEEP SYSTEM</b>
<b>SPECIAL 510(k) DEVICE MODIFICATION</b>	JUNE 17, 2002 PAGE 51 of 53

## Section G – INDICATIONS FOR USE

510(k) Number (if known): K022037

Device Name: SLEEP System

### Indications for Use:

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- Digital recording of high-level output signals (such as EEG, respiratory and oximetry signals) from conventional polygraphic recorders, signal transducers or amplifiers.
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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
 (Per 21§ CFR 801.109)

OR Over-The Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
 (Division Sign-Off)  
 Division of General, Restorative  
 and Neurological Devices

510(k) Number K022037